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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,246	06/25/2004	Jun Watanabe	4924-0102PUS1	8918
2292	7590	12/14/2005	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			HAMPTON HIGHTOWER, PATRICIA	
		ART UNIT	PAPER NUMBER	
		1711		

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/500,246	WATANABE ET AL.
	Examiner Patricia Hightower	Art Unit 1711

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 4/22/05; 6/25/04.
- 2a) This action is **FINAL**.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-9 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>6/25/04; 4/22/05</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

***Information Disclosure Statement***

The information disclosure statements filed June 25, 2004 and April 22, 2005 have been considered and have been made of record.

Claims 4-6 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer back. See MPEP § 608.01(n). Accordingly, the claims 4-6 have not been further treated on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 7, in line 2 of each claim, the terminology "characterized by" is considered to render the claims indefinite in that it is not clear what the applicants mean to convey by use of said terminology. It is suggested to conform to U.S. practice that the applicants delete the terminology "characterized by" from the claims 1 and 7.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process for the continuous production of  $\epsilon$ -caprolactone polymer that is a copolymer of a polymer having a hydroxyl group and/or

an ester bond (i.e., polyester or cellulose ester see page 10 of specification) and  $\epsilon$ -caprolactone (see specification at page 4, lines 18-23) and at page 6, lines 22 – page 7, lines 1-6,7-10,11-21,22-24, the applicants define the  $\epsilon$ -caprolactone polymer as a polymer that can be obtained by ring-opening polymerization of  $\epsilon$ -caprolactone using a compound containing an active hydrogen such as alcohol, amine or water, an organometallic compound, a metal alkoxide or the like as an initiator in the absence or presence of a catalyst and there may be used cyclic esters inclusive of cyclic ester of two hydroxycarboxylic acid molecules and a lactone; and the  $\epsilon$ -caprolactone may be copolymerized with one kind or more of lactones (see specification page 7, lines 22-24 to page 8, lines 1-8,9-24) or a cyclic ester of two hydroxycarboxylic acid molecules. does not reasonably provide enablement for a process for a continuous production of an  $\epsilon$ -caprolactone polymer comprising polymerization of  $\epsilon$ -caprolactone singly or with other compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. It is not clear what the scope of the "with other compound" in claim 7 that the applicants are contemplating. Clarification is requested.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Lowhardt (USP 3,767,627) or Suizu et al (USP 5,496,923).

Lowhardt (USP 3,767,627) discloses an improved process for the preparation of polylactones having blocked end-groups wherein a polylactone, a mixture of polylactones or a mixture of polylactone and lactone monomer is reacted in the presence of a catalyst with at least one modifier which contains at least one ester group not included in a lactone ring and which carries no reactive hydrogen substituents. The starting material may be a homo-polylactone, a copolylactone or a mixture of polylactones obtained by polymerization of one or several polymerizable lactones (i.e., poly- $\epsilon$ -caprolactone, etc.). These polylactones are easily accessible and thermally stable. See col. 1, lines 13-21,25-40,45-53,54-72; col. 2, lines 12-20,21-29,30-43,44-59; col. 3, lines 7-17,18-40,41-70,71-75; col. 4, lines 1-8,9-36, especially 37-47; examples I-II,IV,V-VI,VIII,IX, Tables 2,3,4; claims 1-6.

Lowhardt'627 teaches at col. 2, lines 50-59 that with a single type of preferably high molecular weight polylactone being used as a starting material, the process offers the possibility of preparing a variety of blocked polylactones with markedly different properties by carefully selecting of the type and amount of modifier added and the type and amount of lactone monomers or additional polylactones which may also be added to the reaction mixture.

The patentee teaches at col. 3, lines 15-75, the compounds suitable for use as a modifier have at least one ester group that is not included in a lactone ring and do not carry reactive hydrogen substituents such as ethyl acetate, dibenzyl adipate, dimethyl

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thiapimelic acid diethyl ester, dimethyl terephthalate, etc. It can therefore be seen that different organic mono-, di-, tri- and tetra-esters and other polyvalent esters may be employed as modifiers provided they do not carry interfering reactive hydrogen substituents such as hydroxyl-, carboxyl- or amino groups. But it is preferred to use modifier that are non-volatile or slightly volatile under the reaction conditions, having the advantage that the process need not be carried out under superatmospheric pressure. If desired, mixtures of different modifiers may also be employed. The starting material may be a homopolylactone, a co-polylactone or a mixture of polylactones obtained by polymerization of one or several polymerizable lactones, i.e., polycapolactone. The molecular weight of the original polylactone is not critical and may be for example 1000 as well as 150,000. The polylactones are easily accessible and thermally stable.

At col. 4, lines 1-47 the patentee teaches the starting polymer maybe a commercial product or a polylactone made a commercial product, or a polylactone made a considerable time before the modification. It is also possible to mix freshly prepared polylactone with a modifier and allow these to react or to add modifier and allow these to react or to add modifier to a polylactone that is still in the polymerization reactor. In the two latter cases, the polylactone usually still contains sufficient active catalyst. The simplicity of feeding can be achieved by mixing the catalyst and/or the modifier with a lactone or a mixture of lactones prior to the reaction and supplying this mixture to the reactor. The reaction can be carried out at temperatures between about 60°C and 300°C but preferably at a temperature between about 100 and 200°C. To avoid degradation of the polymer and discoloration it preferred to carry out the

modification in the absence of oxygen and water, for example in a dry nitrogen atmosphere. The pressure at which the reaction is carried out is not critical and may be atmospheric, superatmospheric or below atmospheric.

The procedure for performing the reaction comprises heating a polylactone melt to the required temperature, adding modifier, and adding the catalyst should this be necessary and allowing the mixture to react for 0.5 – 4 hours at elevated temperature in a dry nitrogen atmosphere and if possible with simultaneous agitation. If desired, the catalyst can be deactivated and removed in a known manner after the reaction (removing the precipitate by filtration and followed by washing and drying). The reduced viscosity mentioned in these examples was determined on solutions of 0.4 g of polymer in 100 ml of chloroform at 30°C.

Claims 1-3 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Suizu et al (USP 5,496,923).

Suizu et al (USP 5,496,923) discloses a purification process for an aliphatic polyester prepared in the presence of a catalyst for a hydroxycarboxylic acid or a cyclic ester of a hydroxycarboxylic acid or a combination of an aliphatic polyhydric alcohol with an aliphatic polybasic acid or a mixture of these compounds comprising deactivating the catalyst while maintaining the aliphatic polyester in a molten or dissolved state or insolubilizing and separating the catalyst and successively removing low molecular compounds. The process can provide aliphatic polyester that has a low content of unreacted monomers and low molecular weight compounds and is excellent in heat resistance and weatherability. See abstract.

The patentee teaches at col. 2, lines 63-67 – col. 3, lines 1-35,40-67; col. 4, lines 1-4,5,9-10, 35-38,66-67; the purification process for removing cheaply and with ease in industry the low molecular weight compounds such as unreacted monomer and volatile substances which remain in the aliphatic polyester obtained by polycondensation reaction and to obtain the aliphatic polyester which has a low residual amount of the unreacted monomer and low molecular weight volatile substances and is excellent in heat resistance and weatherability. The patentee teaches an aliphatic polyester which has a low content of a low molecular weight compound and is excellent in heat resistance and weatherability can be obtained by deactivating a catalyst or by bringing an organic solvent solution of the aliphatic polyester into contact with an acid material to insolubilize and remove the catalyst in the aliphatic polyester while maintaining the aliphatic polyester in a molten or dissolved state and successively conducting distillation or crystallization to remove the low molecular compound contained in the aliphatic polyester.

Suizu'923 teaches at col. 3, lines 40-67- col. 4, lines 1-4, the aliphatic polyester which can be used is a homopolymer or copolymer which is prepared from a hydroxycarboxylic acid or cyclic ester or the hydroxycarboxylic acid, a polyester prepared by reacting an aliphatic polyhydric alcohol with an aliphatic polybasic acid and a polyester prepared from a mixture of these raw materials. These polymers are prepared by direct polycondensation of raw materials or by ring-opening polymerization of a cyclic ester intermediate of hydroxycarboxylic acid in the presence of a catalyst for example by suitably using a copolymerizable monomer such as lactide which is a cyclic

dimer of lactic acid, glycolide which is a dimer of glycolic acid and  $\epsilon$ -caprolactone which is a cyclic ester of 6-hydroxycaproic acid.

The patentee teaches the ring-opening polymerization of the cyclic ester of hydroxycarboxylic acid is usually carried out without solvent and thus the polymer is in a molten state. The direct dehydration polycondensation is carried out in a solvent and thus the polymer is dissolved in the solvent. The polymerized mass of the aliphatic polyester obtained by polymerization process contains several percents of unreacted raw materials, chain and cyclic oligomers and other low molecular weight compounds; an active catalyst used for the polymerization and a solvent depending upon the polymerization processes. The process deactivates the catalyst while maintaining the aliphatic polyester thus obtained in a molten or dissolved state or insolubilizes and separates the catalyst and successively removes the lower molecular weight compounds. The aliphatic polyester obtained by ring opening polymerization contains the polymer in a molten state after finishing the polymerization and thus purification is more readily carried out in view of operations by deactivating the catalyst and successively removing the low molecular compounds. On the other hand, the aliphatic polyester obtained by direct dehydration polycondensation in a solvent is preferably purified by insolubilizing and separating the catalyst and successively removing the low molecular weight compounds. Low molecular weigh compounds include oligomers having a molecular weight of 500 or less and unreacted raw materials. Particularly, cyclic esters of hydroxycarboxylic acids, for example  $\epsilon$ -caprolactone are removed. See

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col. 5, lines 1-10,11-30,58-64; col. 6, lines 4-12, 13-50, 51-56,60-63; col. 7, lines 6-45,58-63.

Suizu et al '923 teaches after insolubilizing the catalyst, the aliphatic polyester solution contains residual acidic substance. The acidic substance sometimes decomposes the aliphatic polyester in the steps such as concentration for **isolating** the aliphatic polyester and thus must be neutralized depending on successive operations, if desired. After finishing neutralization, insoluble matter and the insolubilized catalyst are **removed by filtration to obtain an aliphatic polyester solution that does not contain insoluble matter.** See col. 6, lines 50-67.

Suizu et al '923 teaches at col. 7, lines 6-57, after deactivating the catalyst or insolubilizing and removing the catalyst by these operations, the aliphatic polyester is isolated by removing the low molecular weight compounds. Removal of the low molecular weight compounds can be carried out for example by dissolving the aliphatic polyester in a solvent and cooling the solution to crystallize the aliphatic polyester by adding a lean solvent to the aliphatic polyester solution and precipitating the aliphatic polyester solution. The low molecular weight compounds are preferably removed by distillation. Distillation of the low molecular weight compound means distillation of the low molecular weight compound dissolved in the solvent and evaporation of the low molecular weight compound contained in the polymer. Distillation conditions for isolating the aliphatic polyester depend upon the equipment for carrying out distillation. The distillation is usually carried out at 300°C or less, a preferred temperature is 250°C or less. On the other hand when the temperature is too low, a prolonged time is

required for distillation removal of low molecular weight compounds. Thus, a preferred temperature is 120°C or more. The pressure in the system depend upon the operation temperature and is usually 50 mmHg or less, preferably 10 mmHg or less, more preferably 5 mmHg or less. The time required for removing the low molecular weight compounds by distillation differs, depending upon the kind of aliphatic polyester, distillation temperature, level of pressure reduction and distillation temperature, level of pressure reduction and distillation equipment. Distillation time can be still more reduced by further reducing the distillation pressure and maintaining high vacuum.

***Prior Art***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. These references are cited to show the state of the art of preparing hydroxyl-terminated polylactones and a process of purifying aliphatic polyester; Lowhardt'495 and Suizu'767.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Hightower whose telephone number is (571) 272-1073. The examiner can normally be reached on M-F from 9:30 A.M. - 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Primary Examiner  
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November 14, 2005